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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,697	02/12/2001	Hagan P. Bayley	4210.001200	1449

7590 05/02/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/02/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,697	BAYLEY ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 39-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Sequence Compliance

1. Applicant's compliance of the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures in Paper No. 13 is acknowledged. The computer readable form of the "Sequence Listing" has been submitted and entered in Paper No. 14.

Amendment

2. Applicant's amendment of Claim 32 in Paper No. 12 is acknowledged and entered.

Election/Restrictions

3. Applicant's election with traverse of Group IV, Claims 32-38 in Paper No. 12 is acknowledged.

Applicant has decided that the restriction between Claims 1-31, Groups I-III, and Claims 32-43, Groups IV-VII as related to composition (product) and method of using the compositions (process of use) is proper. Applicant argue that the different features between Groups I-III and those between Groups IV-VII does not justify they be restricted and there is no burden in the search because of overlapping features. Therefore, Groups I-III should be rejoined into a single group and also that Groups IV-VII be rejoined into a single group.

This is not found persuasive because the search requirement is *not* co-extensive that a search for one invention within either Groups I-III or Groups IV-VII would *not encompass* the limitations of the other inventions thus resulting in divergent of the search evaluations. And one

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of the two criteria for a proper requirement for restriction between patentably distinct inventions is that the inventions must be independent or distinct (see MPEP 803 under Criteria for restriction).

Groups I-III are independent inventions. Each group is a different composition in which the different features produce a different effect. The feature of a modified pore-subunit polypeptide assembling into an oligomeric pore assembly of group I (Claims 1-23) is not required by the claims of either Groups II or III. The feature of a staphylococcal alpha hemolysin pore-subunit polypeptide of group II (Claim 24) is not required by the claims of either Groups I or III. The feature of forming a pore of group III (Claims 25-31) is not required by the claims of either Groups I or II. Groups IV-VII are independent inventions. Each group is a different method of detection that involves different method steps. In Group IV (Claims 32-38), the method steps involve in the detection of the presence of the analyte in the sample in which case the analyte can be either known or unknown. In Group V (Claim 39), the method steps would determine the identity of an unknown analyte in the sample. In Group VI (Claims 40-41), the method steps would detect the change in the type or amount of biological or chemical constituent in the sample. In Group VII (Claims 42-43), the method steps would detect the change in the physical environment of the sample.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

4. The listing of references in the specification, pages 61-65, is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other

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information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) Claim 32 is vague and indefinite because it is unclear how the sensing moiety is related to the analyte. In other words, what is the function of the sensing moiety?
- b) Claims 32-34 are vague and indefinite because "a first channel" appears to lack antecedent support. This channel has not previously been defined before its use is recited. How is it related to the pores?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Church et al. (US Patent 5,795,782).

Church discloses a method of detecting an individual polymer molecule by an interface, which comprise an ion permeable passage (col. 1, lines 35-38; col. 2, line 41-44). The ionic conductance of the passage will change as each monomer interacts. The passage is either a protein channel or a recombinant bacterial porin molecule (col. 3, line 38; col. 4, lines 57-67; fig. 2). The protein channel is assembled by covalent linkage by expressed protein (col. 3, line 38-55). The channel also includes a receptor that interacts with the polymer (col. 3, lines 28-36). The electrical current can be detected through a single channel (col. 7, lines 10-15; fig. 1 and 2) or two channels system (fig. 1 and 2). The method can also identify the individual monomers in the polymer (col. 5, lines 27-36). The polymer is any biological polymer such as DNA (col. 1, lines 59-65). The concentration of the polymer can be determined (col. 2, lines 48-58). Church method anticipates the claimed invention.

9. Claims 32-33, 35 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Braha et al. (*Chemistry & Biology*, 4(7):497-505, 1997).

Braha discloses a method of detecting divalent metal ions using a bacterial pore-forming proteins, which has receptor sites and information-rich signal can be obtained by single-channel recording (pg. 498, left col., line 6 to right col., lines 1-4; pg. 502, right col., lines 8-11). The divalent metal ions of interest are Co(II), Ni(II), and Cu(II) (pg. 501, left col., lines 24-26). The concentration and identity of the analytes is determines by the single-channel currents to membrane potential (pg. 502, left col., lines 1-3). Braha method anticipates the claimed invention.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following prior art teaches method of detection using ion channel: Cornell et al. (US Patent 5,443,955) and Osman et al. (US Patent 5,234,566).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

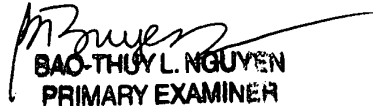
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
May 1, 2002


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
5/1/02